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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,644	09/18/2001	Eric Silverberg	1893	1184

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/955,644

Applicant(s)

SILVERBERG ET AL.

Examiner

Isis A. Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/19/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' request for RCE, IDS, and amendment, all filed 12/19/2006.

Claims 1-20 have been pending, and claim 21 has been added.

Claims 1-21 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/19/2006 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,491,070 ('070).

The present claim is interpreted as require polymer prepared from monomer selected from the group consisting of monomers selected from the group consisting of: alkyl acrylate, alkyl methacrylate monomer and polymerizable non-cyclic nitrogen-containing monomer. Further the claims require 50-98% alkyl acrylate monomers and/or alkyl methacrylate monomers.

US '070 disclosed excellent pressure sensitive adhesive with good tack obtained by the combination of monomers to form polymers consisting of 80-96% of 2-ethylhexyl acrylate and 2.0-19% of octyl acrylamide to create a polymer combination that is synergistic in nature (col.1, lines 52-60). The Tg as claimed by claim 4 is inherent for specific polymer.

4. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,988,567 ('567).

The present claim 1 is interpreted as require polymer prepared from monomer selected from the group consisting of monomers selected from the group consisting of:

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alkyl acrylate, alkyl methacrylate monomer and polymerizable non-cyclic nitrogen-containing monomer. Further the claims require 50-98% alkyl acrylate monomers and/or alkyl methacrylate monomers.

US '567 disclosed polymer formed of at least 70 % of alkyl acrylate such as 2-ethylhexyl acrylate and up to 30% of octyl acrylamide (col.5, lines 19-55). The Tg as claimed by claim 4 is inherent for specific polymer.

5. Claims 1-7, 18, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,391,406 ('406).

The present claim 1 is interpreted as require polymer prepared from monomer selected from the group consisting of monomers selected from the group consisting of: alkyl acrylate, alkyl methacrylate monomer and polymerizable non-cyclic nitrogen-containing monomer. Further the claims require 50-98% alkyl acrylate monomers and/or alkyl methacrylate monomers.

US '406 disclosed polymer composition that remain stable during processing and after coating on a substrate made of polymerizing 80% 2-ethylhexyl acrylate and up to 20% of vinyl monomer including t-octyl acrylamide (col.2, lines 47-50, 64-68; col.3, lines 42-60). The polymer has Tg in the range of -60°C to $+5^{\circ}\text{C}$ (col.3, lines 3-10). The acrylate monomer may further contain other acrylate monomers such as methyl acrylate that are not tacky or pressure sensitive (col.3, lines 61-68; col.6, lines 46-52; col.11, lines 25-40; col.12, lines 22-27).

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6. Claims 1-6, 8-17 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/08229 ('229).

The present claims 1 and 12 interpreted as require polymer prepared from monomer selected from the group consisting of monomers selected from the group consisting of: alkyl acrylate, alkyl methacrylate monomer and polymerizable non-cyclic nitrogen-containing monomer. Further the claims require 50-98% alkyl acrylate monomers and/or alkyl methacrylate monomers.

WO '229 disclosed pressure sensitive adhesive composition comprising acrylic polymer comprising 40-95% of one or more A monomers selected from the group consisting of alkyl acrylates having 4-10 carbon atoms and alkyl methacrylates having 4-10 carbon atoms, and up to 60% of one or more B monomers (page 2, lines 5-23). The preparations disclosed by WO '229 all contain the optional B monomer such as vinyl acetate and dimethylacrylamide. Preferred A monomers include 2-ethylhexyl acrylate, n-butyl acrylate, and methyl methacrylate (page 4, lines 3-14). B monomers include substituted acrylamide, methacrylonitrile, and vinyl acetate, which read on polymerizable non-cyclic nitrogen-containing monomer (page 4, lines 25-27; page 5, lines 7-12). Additionally, the macromonomer disclosed by WO '229 read on both alkyl acrylate and/or alkyl methacrylate instantly claimed. WO '229 on page 8, lines 15-19, gave examples of the macromonomers as those disclosed by US '4,732,808, and by careful review of that patent it became apparent that such macromonomers contain from 4-12 carbon atoms, col.5, lines 28-33. Therefore, the macromonomers disclosed by WO '229 contain up to 18 carbon atoms as evidenced by US '808. Applicants'

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polymer as claimed can contain both alkyl acrylate and/or alkyl methacrylate, and WO '229 disclosed monomer A is alkyl acrylate and the macromonomer is alkyl methacrylate. On page 18, lines 1-5, WO '229 disclosed copolymer preparation of alkyl acrylate: dimethylacrylamide: polymethacrylate at a ratio of 50:40:10, i.e. total amount of alkyl acrylate and alkyl methacrylate together is 60% and the amount of non-cyclic nitrogen containing monomer is 40%. On page 18, lines 14-17, WO '229 disclosed same preparation of alkyl acrylate: dimethylacrylamide: polymethacrylate but at a ratio 63:27:10, i.e. total amount of alkyl acrylate and alkyl methacrylate together is 73% and the amount of non-cyclic nitrogen containing monomer is 27%. The preparation on page 22 of WO '229, lines 15-18 is alkyl acrylate: vinyl acetate: polymethacrylate at a ratio of 58:37:5, i.e. total amount of alkyl acrylate and alkyl methacrylate together is 63% and the amount of non-cyclic nitrogen containing monomer is 37%. On page 23, lines 14-17, WO '229 disclosed same preparation of alkyl acrylate: vinyl acetate: polymethacrylate at a ratio of 53:37:10, i.e. total amount of alkyl acrylate and alkyl methacrylate together is 63% and the amount of non-cyclic nitrogen containing monomer is 37%. Therefore, WO '229 disclosed the claimed polymer formed of the same monomers at ranges within the claimed ranges. WO '229 meets the limitation of claims 1-6 and 8-17. The polymer composition as disclosed by WO '229 is used to form matrices for transdermal drug delivery device (page 2, lines 5-13; page 3, lines 29-30). The transdermal device comprises a backing layer, a matrix layer comprising the polymer composition and a therapeutic active agent, and a release liner (page 2, line 6; page 13, line 22; page 14, lines 16-17, 26). WO '229 further contemplates various drugs for delivery by the device

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including analgesics such as fentanyl (page 12, line 28). The pressure sensitive adhesive has a glass transition temperature of -10^0 C (page 11, lines 4-5). The reference does not teach any cross-linking agent in the polymer composition or any functional groups containing reactive hydrogen.

Response to Arguments

7. Applicant's arguments filed 12/19/2006 have been fully considered but they are not persuasive. Applicants traverse the anticipatory rejection of claims 1-6 and 8-17 over WO 229 by arguing that the reference does not anticipated the claims because the claims as amended require that both alkyl acrylate and alkyl methacrylate have up to 18 carbon atoms.

In response to this argument, it is argued that the A monomer and the macromonomer disclosed by WO '299 read on the alkyl acrylate and/or alkyl methacrylate instantly claimed, and B polymer reads on the non-cyclic nitrogen containing polymer. Applicants' polymer as claimed can contain both alkyl acrylate and/or alkyl methacrylate, and WO '229 disclosed monomer A is alkyl acrylate and the macromonomer is alkyl methacrylate. The macromonomer disclosed by WO '299 read on both alkyl acrylate and/or alkyl methacrylate instantly claimed. WO '229 on page 8, lines 15-19, gave examples of the macromonomers as those disclosed by US '4,732,808, and by careful review of that patent it became apparent that such macromonomers contain from 4-12 carbon atoms, col.5, lines 28-33. Therefore, the macromonomers disclosed by WO '229 contain up to 18 carbon atoms as evidenced by

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US '808. In any event, applicants' attention is drawn to the claims language that requires polymer prepared from monomers selected from the group consisting of: alkyl acrylate, alkyl methacrylate monomer and polymerizable non-cyclic nitrogen-containing monomer. Therefore, the claims can be polymer on any one of the above 3 monomer. Further, the claims recite the polymer comprises 50-98% of alkyl acrylate monomers and/or alkyl methacrylate monomers. Therefore, the claims language does not require both alkyl acrylate monomers and alkyl methacrylate monomers.

8. Claims 1-11, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,077,527 ('527).

The present claim interpreted as require polymer prepared from monomer selected from the group consisting of monomers selected from the group consisting of: alkyl acrylate, alkyl methacrylate monomer and polymerizable non-cyclic nitrogen-containing monomer. Further the claims require 50-98% alkyl acrylate monomers and/or alkyl methacrylate monomers.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US '527 disclosed a pressure sensitive adhesive composition for use in transdermal drug delivery devices comprising at least 40% by weight of alkyl acrylate including n-butyl and 2-ethylhexyl acrylate, and 10-60% by weight of substituted acrylamide or methacrylamide including t-octyl acrylamide (abstract; col.2, lines 45-60; col.3, lines 60-67; col.4, lines 8-16). The Tg of the composition is calculated by the examiner to be below 10⁰C. The reference does not disclose any reactive groups after the cross-linking.

Response to Arguments

9. Applicant's arguments filed 12/19/2006 have been fully considered but they are not persuasive. Applicants traverse the anticipatory rejection of claims 1-11 and 14 over US '527 (Tan's reference) by arguing that US '527 does not disclose any acrylic polymer that contains only alkyl (meth) acrylate monomers and polymerizable non-cyclic nitrogen-containing monomer.

In response to this argument, applicants' attention is drawn to the claims language that requires polymer prepared from monomers selected from the group consisting of: alkyl acrylate, alkyl methacrylate monomer and polymerizable non-cyclic nitrogen-containing monomer. Therefore, the claims can be polymer of any one of the above 3 monomer. Further, the claims recite the polymer comprises 50-98% of alkyl acrylate monomers and/or alkyl methacrylate monomers. Therefore, the claims language does not exclude other polymers.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 7 are rejected under 35 U.S.C. 103(a) as being obvious over WO 96/08229 ('229) in view of US '070.

The teachings of WO '229 and US '070 are discussed above.

WO '229 does not teach the specific octyl acrylamide claimed in claims 7, which is taught by US '070 to have a good tack when combined with 2-ethylhexyl acrylate creates a polymer combination that is synergistic in nature.

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Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver polymer adhesive composition made of alkyl acrylate monomer and acrylamide monomer as disclosed by WO '229, and replace the acrylamide monomer with octyl acrylamide disclosed by US '070, motivated by the teaching of US '070 that the combination of alkyl acrylate and octyl acrylamide has a good tack and creates a polymer combination that is synergistic in nature, with reasonable expectation of having polymer adhesive composition made of alkyl acrylate monomer and octyl acrylamide monomer that has good tack and synergistic adhesive nature.

13. Claims 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '229 in view of US 5,458,885 ('885).

The teachings of WO '229 are discussed above.

However, WO '229 does not teach the acrylate polymer comprises 2-ethylhexyl acrylate and methyl acrylate as required by claims 18 and 20.

US '885 teaches transdermal system comprising polymer made of methyl acrylate and 2-ethylhexyl acrylate wherein the polymer is suitable to deliver basic active agents and their salts including analgesics (col.2, lines 43-55; col.3, lines 3-9, 64-67; col.4, lines 1-50; col.6, lines 37, 50-60; col.7, lines 1-9).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver polymer adhesive composition made of alkyl acrylate monomer and acrylamide monomer as disclosed by WO '229, and replace the acrylate

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monomer with polymer made of methyl acrylate and 2-ethylhexyl acrylate as disclosed by US '885, motivated by the teaching of US '885 that such a polymer is suitable to deliver basic active agents and their salts including analgesics, with reasonable expectation of having polymer adhesive composition made of alkyl acrylate monomer made of 2-ethylhexyl acrylate and methyl acrylate and acrylamide monomer wherein the polymer provides successful delivery to basic therapeutic agents including analgesics.

14. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '229 in view of US '885 and further in view of US '070.

The combined teaching of WO '229 and US '885 are discussed above.

However, the combined teaching of the references does not teach octyl-acrylamide that is taught by US '070.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polymer adhesive composition made of alkyl acrylate monomer made of 2-ethylhexyl acrylate and methyl acrylate and acrylamide monomer as taught by the combined teaching of WO '229 and US '885, and replace the acrylamide with octyl acrylamide as taught by US '070, motivated by the teaching of US '070 that the combination of alkyl acrylate and octyl acrylamide has a good tack and creates a polymer combination that is synergistic in nature, with reasonable expectation of having polymer adhesive composition made of alkyl acrylate monomer comprising 2-ethylhexyl acrylate and methyl acrylate, and octyl acrylamide monomer that has good tack and synergistic adhesive nature.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis A Ghali
Primary Examiner
Art Unit 1615

IG

Isis Ghali

**ISIS GHALI
PRIMARY EXAMINER**